

# The clinical efficacy of hydrogen combined with tetrandrine in the treatment of silicosis fibrosis

<b>Submission date</b> 22/09/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/09/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 23/09/2025	<b>Condition category</b> Respiratory	<input checked="" type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study looked at whether combining hydrogen inhalation with a medicine called tetrandrine could help people with stage II silicosis, a lung disease caused by breathing in dust over many years. The researchers wanted to see if this combination could improve lung function, exercise ability, and symptoms better than tetrandrine alone.

### Who can participate?

Adults aged 50 to 80 years old who had been diagnosed with stage II silicosis and had at least five years of dust exposure could take part. People with certain other health conditions, such as tuberculosis, severe chronic obstructive pulmonary disease, serious kidney or liver problems, or cancer, were not included.

### What does the study involve?

Participants were randomly assigned to one of two groups. One group received tetrandrine tablets and inhaled a mixture of oxygen and nitrogen. The other group received tetrandrine tablets and inhaled a mixture of oxygen and hydrogen. Both treatments lasted for several months. The researchers measured lung function, exercise ability, symptoms, and blood markers before and after treatment.

### What are the possible benefits and risks of participating?

The possible benefit was improved lung function and symptoms for people with silicosis. As with any medical study, there could be risks from the treatments or side effects from the medicines, but these were monitored by the study team.

### Where is the study run from?

The study was run at the Laizhou Chronic Disease Prevention and Treatment Hospital in Laizhou City, Shandong Province, China.

### When is the study starting and how long is it expected to run for?

October 2023 to September 2025.

who is funding the study?  
Laizhou Chronic Disease Prevention and Treatment Hospital (China)

who is the main contact?  
Dr Kang Xiao, cpuokkkkk@163.com

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Kang Xiao

### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

Observation on the clinical efficacy of hydrogen-oxygen aerosol inhalation in the treatment of pneumoconiosis

### Study objectives

We aim to evaluate the efficacy between tetrandrine (Tet) alone and in combination with hydrogen (H<sub>2</sub>) inhalation in patients with stage II silicosis.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 26/08/2023, Lai Zhou City Chronic Disease Prevention and Control Hospital Ethics Committee (NO 738 Wenhua east Road, Laizhou City, Shandong, Laizhou City, 261400, China; +86 134 0535 5531; 1228297211@qq.com), ref: NO.MXBFZY-2023-03

### Study design

Single-center interventional randomized controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment, Efficacy

## Health condition(s) or problem(s) studied

Silicosis

## Interventions

We used blocking randomisation. Staff other than participants, care providers, outcome assessors, data analysts generated the random allocation sequence. Random numbers include 1 and 2. The patients were evenly divided into 6 groups based on their smoking status. Each group of patients drew lots to determine their group assignment. Those who drew odd numbers were assigned to the control group, while those who drew even numbers were assigned to the treatment group. The treatment plan for each research subject is generated by a randomly assigned sequence and is placed in an ordered, sealed, and opaque envelope. The envelope can only be opened when a qualified subject agrees to participate in the trial, and then the subject can receive the corresponding treatment measures. The personnel who enrolled and those who assigned participants to the interventions could not access to the random allocation sequence. Participants, care providers, outcome assessors, data analysts were blinded after assignment to interventions. To ensure the implementation of blinding, the same hydrogen-oxygen machine and control machine were used for the experiment.

Control group: Tetrandrine oral administration, 60mg, tid, for 6 consecutive days, followed by a 1-day break combined with mixture of oxygen (33%) and nitrogen (67%) (flow: 3L/min) inhalation 2h per day.

Treatment group: Tetrandrine oral administration, 60mg, tid, for 6 consecutive days, followed by a 1-day break combined with mixture of oxygen (33%) and hydrogen (67%) (flow: 3L/min) inhalation 2h per day.

## Intervention Type

Device

## Phase

Phase I/II

## Drug/device/biological/vaccine name(s)

Hydrogen-oxygen machine

## Primary outcome(s)

Diffusion Lung capacity for CO measured using pulmonary function testing equipment after 6 months treatment

## Key secondary outcome(s)

1. Forced vital capacity measured using pulmonary function testing equipment after 3 and 6 months treatment
2. Forced expiratory volume in one second measured using pulmonary function testing equipment after 3 and 6 months treatment

3. Diffusion Lung capacity for CO measured using pulmonary function testing equipment after 3 months treatment
4. Modified Medical Research Council measured using questionnaire after 3 and 6 months treatment
5. COPD Assessment Test measured using questionnaire after 3 and 6 months treatment
6. Walking distance measured using 6 min walk experiment after 6 months treatment
7. Serum IL-6 level measured using ELISA after 3 and 6 months treatment

**Completion date**

01/09/2025

## Eligibility

**Key inclusion criteria**

1. Age: 50 - 80 years old, gender not restricted
2. Diagnosed with stage II silicosis based on medical history and related examinations
3. Dust exposure  $\geq$  5 years
4. Voluntary signing of the informed consent form

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

50 years

**Upper age limit**

80 years

**Sex**

All

**Total final enrolment**

108

**Key exclusion criteria**

1. Patients with a history of tuberculosis or those in the active stage of tuberculosis
2. Pulmonary tumors
3. Severe chronic obstructive pulmonary disease (GOLD level 4)
4. Estimated glomerular filtration rate (eGFR) lower than 30 milliliters per minute
5. Child-Pugh B/C grade
6. Pregnant women

**Date of first enrolment**

23/10/2023

**Date of final enrolment**

01/02/2024

## Locations

**Countries of recruitment**

China

**Study participating centre****Laizhou Chronic Disease Prevention and Treatment Hospital**

NO 738 Wenhua east Road, Laizhou City, Shandong

Laizhou City

China

261400

## Sponsor information

**Organisation**

Laizhou Chronic Disease Prevention and Treatment Hospital, Shandong Province

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Laizhou Chronic Disease Prevention and Treatment Hospital, Shandong Province

## Results and Publications

**Individual participant data (IPD) sharing plan**

The research results have been made public on the Dryad database. DOI: 10.5061/dryad.rfj6q57pp

**IPD sharing plan summary**

Stored in publicly available repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Dataset</a>			23/09/2025	No	No

